

UNITED STATES PATENT AND TRADEMARK OFFICE

Re:	Group:	To be assigned
	Application of:	Anand BAICHWAL
	Serial No.:	To be assigned
	Filed:	Herewith
	For:	Sustained Release Heterodisperse Hydrogel Systems-amorphous Drugs

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
Alexandria, VA 22313-1450

January 27, 2004

Sir:

In accordance with the provisions of 37 C.F.R. § 1.97, Applicants hereby make of record the document listed on the accompanying Form PTO 1449 (11 sheets), enclosed herewith, for consideration by the Examiner in connection with the examination of the above-identified patent application.

The references cited on the accompanying Form PTO 1449 are of record in the Parent U.S. Application Serial No. 09/879,296. Accordingly, under 37 C.F.R. § 1.98(d), copies of these references are not enclosed.

The Examiner's attention is directed to sheet 11 of the enclosed Form-PTO 1449, which lists a reference cited by the Examiner during prosecution of U.S. Application Serial No. 09/879,296. Accordingly, under 37 C.F.R. § 1.98(d) a copy of this reference is also not enclosed.

Applicants also respectfully advise the Examiner of the following commonly assigned U.S. Patents and applications:

U.S. Patent No. 5,455,046; "Sustained Release Heterodisperse Hydrogel Systems for Insoluble Drugs", issued October 3, 1995;

U.S. Patent No. 5,662,933, "Controlled Release Formulation (Albuterol), issued September 2, 1997;

U.S. Patent No. 5,512,297, "Sustained Release Heterodisperse Hydrogel Systems for Insoluble Drugs", issued April 30, 1996;

U.S. Patent No. 5,554,387, "Sustained Release Heterodisperse Hydrogel Systems for Insoluble Drugs", issued September 10, 1996;

U.S. Patent No. 5,667,801, "Sustained Release Heterodisperse Hydrogel Systems for Insoluble Drugs", issued September 16, 1997;

U.S. Patent No. 5,773,025, "Sustained Release Heterodisperse Hydrogel Systems-Amorphous Drugs", issued June 30, 1998;

U.S. Patent No. 5,846,563, "Sustained Release Heterodisperse Hydrogel Systems for Insoluble Drugs", issued December 8, 1998;

U.S. Patent No. 5,958,456, "Controlled Release Formulation (Albuterol), issued September 28, 1999;

U.S. Patent No. 6,093,420, "Sustained Release Matrix for High-Dose Insoluble Drugs", issued July 25, 2000;

U.S. Patent No. 6,245,355, "Sustained Release Matrix for High-Dose Insoluble Drugs", issued June 12, 2001;

U.S. Patent No. 6,056,977, "Novel Once-A-Day Controlled Release Sulfonylurea Formulation", issued May 2, 2000;

U.S. Patent No. 6,048,548, "Sustained Release Heterodisperse Hydrogel Systems-Amorphous Drugs", issued April 11, 2000;

U.S. Patent No. 6,245,356, "Sustained Release Heterodisperse Hydrogel Systems-Amorphous Drugs", issued June 12, 2001;

U.S. Patent No. 6,136,343, "Sustained Release Matrix for High-Dose Insoluble Drugs", issued October 24, 2000;

U.S. Patent Application No. 09/654,691, "Sustained Release Heterodisperse

Hydrogel Sysytems For Insoluble Drugs”, filed September 5, 2000, allowed;

U.S. Patent Application Serial No. 09/842,289, Sustained Release Matrix For High Dose Insoluble Drugs”, filed April 25, 2001, allowed;

U.S. Patent Application Serial No. 09/879,296, “Sustained Release Heterodisperse Hydrogel Systems-Amorphous Drugs”, filed June 12, 2001, allowed.

Pursuant to 37 C.F.R. § 1.98 (a)(2)(iii), the Examiner’s attention is directed to Exhibit A, attached herewith, which contains the following:

(i) allowed claims of U.S. Patent Application Serial No. 09/654,691, which has the same specification as U.S. Patent No. 6,136,343, listed as reference HF on the enclosed Form PTO-1449.

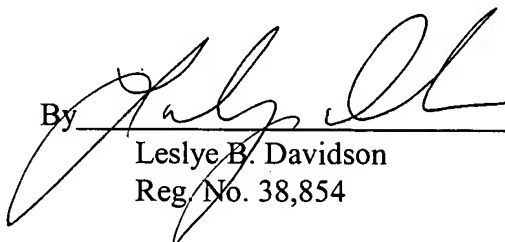
(ii) allowed claims of U.S. Patent Application Serial No. 09/842,289, which has the same specification as U.S. Patent No. 6,245,355, listed as reference IA on the enclosed Form PTO-1449.

(iii) allowed claims of U.S. Patent Application No. 09/879,293, which is the parent application of the application filed herewith, and has the same specification as U.S. Patent No. 6,245,356, listed as reference IB on the enclosed Form PTO-1449.

It is respectfully requested that the references cited on the accompanying Form PTO 1449 be considered and made of record. If any of the publications listed thereon are missing, the Examiner is requested to contact the undersigned so that a copy may be promptly forwarded.

No fee is believed to be due for the submission of this Information Disclosure Statement as it is filed under 37 C.F.R. § 1.97(b), before the mailing of a first Office Action on the merits or within three (3) months of the actual filing date. The Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Attorney Deposit Account No. 50-0552.

Respectfully submitted,
DAVIDSON, DAVIDSON & KAPPEL, LLC

By _____
Leslye B. Davidson
Reg. No. 38,854

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New York, New York 10018
(212) 736-1940

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE				ATTY. DOCKET NO.: 540.91195CP5		SERIAL NO.: To be assigned						
LIST OF PRIOR ART CITED BY APPLICANT						APPLICANT(S): Anand R. BAICHWAL								
(Use several sheets if necessary)														
						FILING DATE: Herewith		GROUP: To be assigned						
U.S. PATENT DOCUMENTS														
*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	AA	4	0	0	3	0	8	1	02/07/89	Falk, et al.	424	488		
	AB	4	8	9	4	2	3	5	01/16/90	Kohne, et al.	424	452		
	AE	5	1	0	8	7	5	7	04/28/92	Erdos, et al.	424	451		
	AD	5	5	5	6	3	8	7	09/10/96	Baichwal	424	488		
	AE	3	4	8	5	0	4	7	12/23/69	Bossert, F., et al.	260	295.5		
	AF	3	7	8	4	6	8	4	01/08/74	Bossert, F., et al.	424	37		
	AG	4	6	8	5	6	8	1	05/12/87	Dol, et al.	514	356		
	AH	4	8	8	0	7	7	3	12/26/89	Kim, et al.	424	450		
	AI	4	9	8	3	5	9	3	01/08/91	Miyajima, et al.	514	110		
	AJ	5	0	1	5	4	7	9	05/14/91	Mulligan, et al.	424	457		
	AK	5	1	2	8	1	6	2	07/07/92	Mulligan, et al.	424	457		
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		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
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	AL	W O	85	0	0	1	0	0	09/26/85	PCT (A1)	A61K	9/40		
	AM	W O	94	2	3	7	0	0	10/27/94	PCT (A1)	A61K	9/16		
	AN	2	7	1	4	6	6	5	10/12/78	Germany (A1)	A61K	9/10		
	AO	3	4	0	0	1	0	6	07/11/85	Germany (A1)	A61K	9/00		
	AP	W O	93	1	3	7	7	3	07/22/93	PCT (A1)	A61K	31/44		
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	AR	Chemical Abstracts, Vol. 104 (1986) Abstract 174662y												
	AS	Chemical Abstracts, Vol. 99 (1983) Abstract 128360d												
	AT	Chemical Abstracts, Vol. 92 (1980) Abstract 135278s												
	AU	Chemical Abstracts, Vol. 92 (1980) Abstract 82429h												
	AV	Chemical Abstracts, Vol. 77 (1972) Abstract 39130g												
	AW	Chemical Abstracts, Vol. 70 (1969) Abstract 17133p												
EXAMINER										DATE CONSIDERED				
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.														

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	BA	5	1	1	0	6	0	2	05/05/92	Kim, et al.	424	451		
	BB	5	1	6	0	2	3	4	11/03/92	Ganesan, et al.	424	78.38		
	BC	5	2	6	4	4	4	6	11/23/92	Hegasy, et al.	514	356		
	BD	4	6	1	2	9	8	6	11/01/83	Kawata, et al.	424	80		
	BF	4	5	0	2	0	6	0	12/31/85	Hegasy, et al.	424	80		
	BF	4	6	7	3	5	0	4	06/16/87	Kawata, et al.	424	494		
	BC	4	7	6	5	9	0	0	08/23/55	Sugimoto, et al.	424	494		
	BH	4	7	9	2	4	5	2	12/20/88	Howard, et al.	424	475		
	BI	4	8	0	8	4	1	3	02/28/89	Joshi, et al.	424	458		
	BI	4	8	6	7	9	8	5	09/19/89	Heafield, et al.	424	461		
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		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
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	BL	0	1	4	7	1	7	1	07/03/85	EPO (A1)	C07D	401/12		
	BM	2	1	0	1	0	8	0	02/06/94	Canada (A1)	A61K	31/44		
	BN	2	1	6	0	1	0	3	12/18/95	Great Britain (A1)	A61K	9/22		
	BO	0	2	3	2	1	5	5	08/12/97	EP (A2)				
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	BP	Chemical Abstracts, Vol. 98 (1983) Abstract 221832y												
	BQ	Alderman, D.A., "A Review of Cellulose Ethers in Hydrophilic Matrices for Oral Controlled-Release Dosage Forms," <u>Int. J. Pharm. Tech. & Prod. Mfg.</u> , Vol. 5, pages 1-9 (1984)												
	BR	Haynes, R. Brian, M.D., et al., "Manipulation of the therapeutic regimen to improve compliance: Conceptions and misconceptions," <u>Clinical Pharmacology and Therapeutics</u> , Vol. 22, No. 2, (August 1977)												
	BS	English translation of Japanese Patent Laid-Open-To-Public, publication no. 8/1986, publication date 1/6/86, Japanese Patent Application No. 118,789/1984; Japanese Patent Application date: 6/9/84												
	BT	<u>Techniques of Solubilization of Drugs</u> , edited by Samuel H. Yalkowsky, The Upjohn Company, pub. Marcel Dekker, Inc., New York and Basel, pages 308-315 (1981)												
EXAMINER										DATE CONSIDERED				
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*EXAMINER INITIAL	CA	DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	CA	5	4	3	9	6	8	7	08/08/95	Compassi	424	468		
	CB	5	3	7	6	6	5	4	12/19/95	Conte, et al.	424	78.08		
	CC	4	9	9	2	7	4	1	01/09/90	Ohm, et al.	424	479		
	CD	4	9	0	4	6	9	9	02/27/90	Bauer	514	972		
	CE	4	9	4	2	0	4	0	07/17/90	Ragnarsson, et al.	424	486		
	CF	4	9	7	3	4	6	9	11/27/90	Mulligan, et al.	424	451		
	CG	4	9	9	4	2	7	6	02/19/91	Baichwal, et al.	424	440		
	CH	5	0	0	7	7	9	0	04/16/91	Shell	424	451		
	CI	5	0	5	1	2	6	3	09/24/91	Barry, et al.	424	490		
	CI	5	0	7	1	6	4	2	12/10/91	Lahr, et al.	424	474		
	CK	5	1	2	8	1	4	3	07/07/92	Baichwal, et al.	424	464		
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	CL	4	3	5	7	7	9	3	03/14/90	EP (A1)				
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	CN	W O	92	0	6	6	8	0	04/30/92	PCT				
	CD	1	2	8	8	9	4	9	08/27/91	Canada				
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	CB	"Crystallization and Granulation," Remington's Practice of Pharmacy, 9 th Ed. Chapter XXVII, pages 208-211, 1950												
	CS	Ritschel, Angewandte Blopharmazie, pages 293-302 (1973)												
	CT	Sugimoto, I., et al., "Dissolution and Absorption of Nifedipine from Nifedipine-Polyvinylpyrrolidone Coprecipitate", <u>Drug Development and Industrial Pharmacy</u> , Vol. 6, No. 2, pages 137-161 (1980)												
	CU	Kleinblosem, M., et al., Nifedipine: Kinetics and dynamics in healthy subjects", <u>Clin Pharmacol. Ther.</u> , Vo. 35, No. 6, pages 742-749 (1984)												
	CV	Ramasch, K., et al., "Pharmacokinetics and Metabolism of Nifedipine", <u>Hypertension Supplement II</u> , Vo. 5, No.4, July - August 18-24 (1983)												
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	DA	5	1	3	5	7	5	7	08/04/92	Baichwal, et al.	424	465		
	DB	5	1	4	5	6	8	3	09/08/92	Rhodes	424	451		
	DC	5	4	5	5	6	4	6	10/03/95	Baichwal	424	457		
	DD	4	4	8	0	6	2	3	11/89	Piergiorgio	424	465		
	DE	5	6	6	7	8	0	1	09/16/97	Baichwal	424	457		
	DI													
	DG													
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	DJ													
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	DL													
	DM													
	DN													
	DO													
	DP													
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	DR	McGinity, J.W., et al., "Dissolution and Uniformity Properties of Ordered Mixes of Micronized Griseofulvin and a Directly Compressible Excipient", Drug Development and Industrial Pharmacy, Vol. 11, No. 4, Pages 891-900 (1985)												
	DS	Helbig, J., et al. "Pharmaceutical oral dosage forms of an active agent capable of forming or releasing bicarbonate ions", Pharmaceuticals, (Abstract-98:221837d), vol. 98, page 63 (1983)												
	DT	The Merck Index, pages 848-849, 9 th Ed. (1976)												
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	EA	4	1	9	1	7	7	2	03/04/80	Woog, et al.	424	273R		
	EO	4	7	6	4	3	8	2	08/16/88	Kydonieus, et al.	424	469		
	EC	4	7	9	2	4	5	6	12/20/88	Kydonieus, et al.	424	449		
	ED	4	9	4	0	5	8	7	07/10/90	Jenkins, et al.	424	480		
	EE	9	6	1	9	3	9	7	05/28/91	Woog, et al.	424	473		
	EE	5	1	3	2	1	1	6	07/21/92	Soumac, et al.	424	469		
	EG	5	1	3	3	9	7	4	07/28/92	Paradissis, et al.	424	469		
	EH	5	1	6	9	6	3	8	12/08/92	Dennis, et al.	424	457		
	EI	5	2	1	5	7	5	6	06/01/93	Krishnamurthy	424	488		
	EJ	5	2	6	4	4	5	9	11/23/93	Chelmick-Schorr, et al.	514	646		
	EK	5	2	2	3	7	6	6	12/28/93	Oshlack, et al.	424	480		
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		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
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	EE	0	2	3	4	6	7	0	02/09/87	EP (B1)				
	EM													
	EN													
	EO													
	EP													
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	ER	D.Q.M. Craig, "Polyethylene Glycois and Drug Release", <u>Drug Development and Industrial Pharmacy</u> , 16(17), pages 2501-2526 (1990).												
	ES	Derwent Abstract DE 3400106A												
	ET	Ritschel, Angewandte Biopharmazie, pages 293-302 (1973) with English translation												
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	FA	5	2	8	6	6	8	3	02/15/94	Oshlack, et al.	424	457			
	FB	5	3	5	0	4	6	7	10/18/94	Oshlack, et al.	106	153			
	FC	6	7	6	5	9	8	0	08/23/88	Wong, et al.	424	473			
	FD	5	1	6	9	6	3	9	12/08/92	Baichwal	424	457			
	FF	5	0	9	1	1	8	0	02/25/92	Kuczynski, et al.	424	473			
	FF	5	6	6	7	8	0	1	06/16/97	Baichwal	424	457			
	FG	5	6	6	2	8	3	3	09/02/97	Baichwal, et al.	424	457			
	FH	5	5	1	2	2	9	7	04/30/96	Baichwal	424	451			
	FF	5	7	7	3	0	2	5	06/30/98	Baichwal	424	458			
	FJ	5	6	7	9	1	6	8	09/23/97	Baichwal, et al.	424	458			
	FK	4	3	6	6	7	0	8	08/31/82	Schmitt	128	260			
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		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION		
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	FL														
	FM														
	FN														
	FO														
	FP														
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)															
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	FS														
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																	4 0 5 1 7 2 9	07/25/89	Magruder, et al.	424	457	
																	5 8 4 6 5 6 3	12/8/98	Baichwal	424	457	
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	GQ																					
	GR																					
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	GS																					
	GT																					
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	HA	5	9	5	8	4	5	6	9/28/99	Baichwal, et al	424	489		
	HB	6	0	9	3	4	2	4	7/25/00	Han, et al.	426	42		
	HC	6	0	5	6	9	7	7	5/2/00	Bhagwat, et al.	424	488		
	HD	6	0	4	8	4	5	8	4/11/00	Vogt, et al.	210	603		
	HE	5	3	3	0	7	6	1	7/19/94	Baichwal	424	464		
	HF	6	1	3	6	3	4	3	10/24/00	Baichwal	424	464		
	HG	4	3	0	9	4	0	5	1/5/82	Guley, et al.	424	21		
	HH	5	1	2	8	1	4	3	7/7/92	Baichwal, et al.	424	464		
FOREIGN PATENT DOCUMENTS														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	HI	0	3	1	1	5	8	2	4/12/89	EPO A1	A61K	9/22		
	HJ	0	3	1	1	5	8	2	4/12/89	EPO B1	A61K	9/22		
	HK	WO	93	0	1	8	0	3	2/4/93	PCT	A61K	9/16		
	HL	6	3	1	3	1	3	3	1/26/93	Canada	A61K	9/22		
	HM	2	0	3	4	0	9	6	7/16/91	Canada	A61K	031/19		
	HN	WO	90	0	3	1	6	5	4/5/90	PCT	A61K	9/16		
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	HO	Factors Affecting Prednisolone Release from Hydrogels Prepared with Water-Soluble Dietary Fibers, Xanthan and Locust Bean Gums, Kazunori, et al., Chem. Pharm. Bull. 40(2) 459-462 (1992)												
	HP	Investigation on Rectal Absorption of Indomethacin from Sustained-Release Hydrogel Suppositories Prepared with Water Soluble Dietary Fibers, Xanthan Gum and Locust Bean Gum, Kazunori et al, Biol. Pharm. Bull, 16(4) 391-394 (1993)												
	HQ	Database WPI Derwent Publications Ltd., London GB; AN 81-35085D XP002011749 and JP-A 56030485 (Sansho KK)												
EXAMINER										DATE CONSIDERED				
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.														

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U.S. PATENT DOCUMENTS

[illegible]

FOREIGN PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS															
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION		
													YES	NO	

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

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				FILING DATE: Simultaneously		GROUP: To be assigned	
U.S. PATENT DOCUMENTS							
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	JA						
	JB						
	JC						
	JD						
	JE						
	JF						
	JG						
	JIH						
	JI						
	JJ						
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
							YES NO
	JP						
	JL						
	JM						
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)							
	JN	Abstract of Japanese Patent Publication No. 54-2316 A (01/09/1979)					
	JD	Abstract of Japanese Patent Publication No. 54-46837 A (04/13/1979)					
	JP	Abstract of Japanese Patent Publication No. 5-306225 A (11/19/1993)					
	JQ	Abstract of JP 05077347, Published September 6, 1994					
	JR						
EXAMINER				DATE CONSIDERED			
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				FILING DATE: Simultaneously		GROUP: To be assigned								
U.S. PATENT DOCUMENTS														
*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	JA	5	6	5	6	2	9	6	08/12/97	Khan et al.	424	473		
	JB													
	JC													
	JD													
	JE													
	JF													
	JG													
	JH													
	JG													
	JJ													
FOREIGN PATENT DOCUMENTS														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	JR													
	JL													
	JM													
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	JN													
	JO													
	JP													
	JR													
	JR													
EXAMINER										DATE CONSIDERED				
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